

Remarks

Applicant respectfully requests reconsideration of the rejections in view of the foregoing amendments and the following remarks. Amended or previously amended claims 1, 2 and 7-9 remain pending and new claims 18-23 have been added. Support for new claims 18 and 20 may be found on page 9, lines 12-22 of the specification where Applicants have described selectable, screenable and scoreable marker genes. Support for new claim 22 can be found on page 15, lines 9-18.

I. Rejections under 35 USC §112, second paragraph

The prior set of claims stood rejected under 35 USC §112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. In particular, the Patent Office has objected to certain phrases as lacking clarity or having proper antecedent basis. It is believed that Applicants have clarified the now pending claims to remove these objections and respectfully requests withdrawal of this rejection. In particular, the Markush group in step (a) of claim 1 has been further clarified to more particularly recite each element in the grouping. Also in step (a) of claim 1, the phrase “capable of identifying a transformed plant cell or tissue to be introduced into the plant cell or tissue” has been given further clarity by way of amendment to the claim to refer to “a selectable marker gene that functions in the identification of a transformed plant cell or tissue....” Claim 3 has been cancelled. Regarding the use of the phrase “about” in claims 7-9, Applicants respectfully submit that this term would be readily understood to one of skill in the art of plant tissue culture and transformation. In particular, and as stated on page 15 of the application, co-culture means “the time from when the explant is inoculated with the Agrobacterium culture up to the time in which the Agrobacterium growth is suppressed by the addition of compounds or through processes that inhibit Agrobacterium growth.” It is understood that this time may vary by experimental design and as determined by the plant species being transformed. This variability is described in the application on page 16, lines 21-25. Thus, one knows that the co-culture period may not be exactly “one day” or “three days”, but rather may be approximately within such a time period. Applicants have used the word “about” to describe this inherent variability in the determination of a co-culture period as is understood in the art of plant tissue culture and transformation.

II. Rejections under 35 USC §112, first paragraph, Written Description

The prior set of claims stood rejected under 35 USC §112, first paragraph, as failing to comply with the written description requirement in that the claims contained subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the art that the inventors, at the time the

application was filed, had possession of the claimed invention. In particular, the Patent Office requests identification in the specification of particular words and phrases used in the claims. Applicants respectfully traverse this rejection and request reconsideration.

Regarding the phrase “the group consisting of immature embryos or embryogenic callus from wheat or maize and hypocotyls sections of [sic, or] callus cell suspension cultures from soybean,” the Examiner’s attention is directed to page 12, lines 11-25 and page 13, lines 1-8, where each of immature embryos, embryogenic callus, soybean hypocotyls sections and soybean cell suspension cultures are all identified. Note also Example 6, page 30, lines 13-20 for identification of the soybean explants and Example 5, page 28, lines 26-29 for maize embryogenic callus explant identification. For convenience and to minimize the number of claims, these explants were grouped together in a Markush claim. Applicant could readily make each explant an independent claim, but that would unnecessarily multiply the claims in this application.

Regarding the phrase “capable of identifying a transformed plant cell or tissue to be introduced into the plant cell or tissue,” the Examiner is directed to page 9, lines 12-22 of the specification and more particularly to lines 13-15 where the substantive aspects of the claimed language is found. It should be noted that in the prior claim language, the phrase “to be introduced into the plant cell or tissue” referred to the “genetic component” and not to the “transformed plant cell or tissue.”

Regarding the phrase “a vessel not containing media,” the Examiner is directed to page 15, lines 23-24 where the phrase is found.

Regarding the phrase “the addition of water in an amount of between 50-300 microliters to said vessel at the co-culture step,’ the Examiner is directed to page 16, lines 19-24 for the reference to addition of water to a vessel at the co-culture step and to page 25, Table 4 for the 50-300 microliter range. It is believed that it is understood to one skilled in the art that the volumes described in an Example are indeed exemplary of what can be used with other plants and/or explants.

Regarding the phrase “the co-culture period,” the Examiner is directed to page 16, line 19.

Although Applicants disagree that the specification as filed does not satisfy the written description requirement under 35 USC §112, first paragraph, in order to facilitate prosecution, Applicants have amended claim 1. Applicants therefore submit that the grounds for the rejection has been rendered moot. In light of these remarks, Applicants respectfully request withdrawal of these rejections.

III. Rejections under 35 USC § 112, first paragraph, Enablement

The prior set of claims stood rejected under 35 USC § 112, first paragraph as allegedly not containing subject matter that was described in the specification in such a way as to enable any person skilled

in the art to which it pertains, or with which it is most nearly connected, to make and use the invention commensurate in scope with the claims. Applicants respectfully disagree.

Applicants thank the Examiner for acknowledging that the specification is “enabling for adding 100-300 microliters of water at the co-culture step, wherein the weight of the Agrobacterium-inoculated explant is reduced by up to 30% during the co-culture period.” Applicants respectfully disagree, however, that the specification “does not reasonably provide enablement for all conditions that decrease the weight of Agrobacterium inoculated explants” as identified in the specification itself.

It is well established law that “the enablement requirement is met if the description enables any mode of making and using the invention.” Johns Hopkins University v. CellPro, 152 F.3d 1342, 47 USPQ2d 1705, 1719 (Fed. Cir. 1998) (emphasis added), quoting Engel Indus. V. Lockformer Co., 946 F.2d 1528, 1533, 20 USPQ2d 1300, 1304 (Fed. Cir. 1991). Applicants further submit that disclosure of a single species provides sufficient enabling support if one of skill in the art can, using the state of the art and Applicant’s written disclosures, practice the invention in its full scope without undue experimentation.¹ In re Wands, 858 F.2d 731, 8 USPQ2d 1400 (Fed. Cir. 1988).

The claimed invention is clearly enabled by the present specification. As acknowledged by the Examiner, the specification discloses a method for providing a fertile transgenic plant by adding 100-300 microliters of water at the co-culture step, wherein the weight of the Agrobacterium-inoculated explant is reduced by up to 30% during the co-culture period”. The specification also describes additional method of producing a fertile transgenic plant under treatment conditions such that the weight of the explant was reduced during the co-culture period (specification page 15, lines 5-8) and preferred methods of the invention that utilize “limited or reduced moisture conditions to reduce explant weight after Agrobacterium inoculation” as well as numerous possible means to achieve this result (specification page 15, lines 9-24 and page 16, lines 1-2).

One of skill in the art would readily use the techniques described in the specification for plant transformation and transformation efficiency analysis to determine the efficacy of any one of the alternative methods disclosed in the application. Although preparation and testing of such transformed plants might or might not require a substantial amount of experimentation, such experimentation is not undue because the methods needed to practice the invention were well known, and there is a high level of skill in the art. See footnote 1. The Examiner has identified one method for reducing the weight of an explant that Applicants

¹ Applicants note that the performance of routing and well-known steps cannot create undue experimentation even if it is laborious. See In re Wands, 858 F.2d at 737, 8 USPQ2d at 1404 (Fed. Cir. 1988). Time and difficulty of experiments are not determinative if they are merely routine. MPEP 2164.06, page 2100-186.

do not consider within the scope of their invention, namely physical removal of part of the explant during the co-culture period. It is submitted, however, that one of ordinary skill in the art would not have even considered this option as it would be unreasonable to remove tissue from a transformation process at this stage and would be detrimental to the stated goal of increasing transformation efficiency. The claims should be read and understood from the teachings in the specification and the treatment described by Applicants is one of limited or reduced moisture conditions that can be measured by a reduced weight of the explant. It is not merely reducing the weight of the explant but the treatment conditions that achieve this reduction that is the improvement to plant transformation that is described and claimed herein. The Examiner has provided no support for the statement “[T]he state of the art indicates that it is unpredictable as to what methods of decreasing the weight of the explant would increase transformation efficiency” (Office Action page 5). Similarly, no support is provided for the Examiner’s statement “It is unpredictable what amount of water should be added to the co-culturing medium to decrease the weight of the explant.” Where in the art is either statement described as unpredictable? Applicant has provided examples of how one would conduct such experiments and analysis thereof. While the experiments may be laborious, that does not make them unpredictable. In fact, the Examiner is using Applicants’ successful experimentation against them (see Office Action page 5) by referring to Applicants’ successful results in Table 3 and then concluding that nothing else could work. This is clearly inappropriate.

Regarding the Examiner’s reference to the “co-culture period,” Applicants respectfully submit that the Examiner has again mistook laborious experimentation for “undue experimentation.” The issue is not one of “undue burden” or a “myriad of experiments” (See Office Action page 5, penultimate paragraph), but rather as previously described by an analysis of the Wands factors (*see* footnote 1 *infra*). One of ordinary skill in the art is expected to act rationally and when the claims require a step of “regenerating a fertile transgenic plant” one so skilled would not submit the explant to conditions that would cause “deleterious effects on tissue.” Finding proper conditions, titration experiments if you will, may indeed be laborious, but they are routine. Applicants claims 6-9 are presented as further limitations of the scope of the claims, but should not and cannot be used against Applicants as evidence of any lack of enablement. Applicants’ claims must be read in light of what is described in the specification and not just what is exemplified. Applicant is not obligated to test all possible permutations of its invention and should not be construed as a lack of guidance when the specification describes various alternatives and it would not require undue experimentation to test such alternatives.

In the interest of advancing prosecution on this application, however, Applicant has provided an amended set of claims for consideration. It is submitted that these claims are fully enabled by the

specification and are not of a breadth that would require undue experimentation by one skilled in the art to practice the invention in its full scope. In light of these remarks, Applicants respectfully request withdrawal of these rejections.

IV. Rejections under 35 USC §102

The Patent Office has maintained two separate rejections of the prior set of claims under Section 102(b). Each of these rejections is respectfully traversed and reconsideration requested in view of the newly amended claims and the following remarks.

Claim 1 stood rejected as being anticipated by Chee et al. Contrary to the Examiner's assertion, Chee cannot and does not anticipate the claimed invention. Chee does not describe any soybean explant other than specific regions of a soybean cotyledon whereas the claimed invention specifically claims soybean hypocotyls or soybean callus cell suspension cultures as it pertains to soybean. Cotyledons are botanically distinct from hypocotyls and callus cell suspension cultures. Please see the attached Exhibit A with Webster's Dictionary definitions of hypocotyls, cotyledon and plumule and Exhibit B with a description of callus and cell suspension cultures from the textbook *Plant Tissue and Cell Culture* (Botanical Monographs, Volume 11, Second Edition, Ed. H E Street) that clearly identify that they are not identical to nor disclosed in Chee. The Examiner's attention is also directed to Fig. 2 on page 107 of the Chee reference where the only part of the soybean cotyledon identified as being suitable for transformation is between the arrows. Furthermore, the Chee protocol is more fully described on page 107 (paragraph 4 in Section 3.1) as "inoculations are done at three different points (between the arrows shown in Fig. 2) by forcing a 301/2-gage needle into the plumule, cotyledonary node, and adjacent regions..." indicating that the three recited areas (plumule, cotyledonary node, and adjacent regions) are all between the arrows of Fig. 2 and all are on the cotyledon. Moreover, Chee et al does not disclose any means for reducing the weight of the explant by limiting or reducing the moisture conditions to which the explant is exposed. As such, Chee cannot anticipate the invention of claim 1 and does not disclose the presently claimed invention. This rejection must be withdrawn.

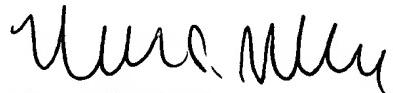
Claims 1 and 2 also stood rejected as being anticipated by Somerville et al (US 568292). The Examiner has now directed Applicants' attention to columns 26, lines 1-3. It is respectfully submitted that the Examiner has either misinterpreted the disclosure on column 26, lines 1-3 or at least failed to read it in its full context. Applicants draw the Examiner's attention to column 25 beginning at lines 61 where it is disclosed that the explant (the axenic leaf pieces) "were transferred to No. 3 medium (MS salts, 30g/L sucrose, 1.2 μ M thiamine, 0.56 mM myoinositol, 1 μ M indole-3-acetic acid, 10 μ M benzylaminopurine, 2.5

mM MES and adjusted to ph 5.6 and solidified with 0.65% agar)...” but there is no reference or disclosure that the explant was at any time removed from this media while being inoculated with the Agrobacterium. In fact, the only way to make the continuing statement in Column 26, lines 3-5 make sense is that the leaf pieces remained in No. 3 media at all times until moved to a modified No. 3 media containing antibiotics. As referenced in these sections, it is clear that Somerville describes a transformation process that utilizes media throughout the process and no co-culture step without media is described. Thus, Somerville cannot be said to disclose each element of the claimed invention. This rejection must be withdrawn.

Conclusion

In view of the above, each of the presently pending claims is believed to be in immediate condition for allowance. Accordingly, the Examiner is respectfully requested to withdraw the outstanding rejections of the claims and to pass this application to issue. Applicant invites the Examiner to call the undersigned for clarification on any aspect of this response or if the Examiner believes that a telephone interview would expedite the prosecution of the subject application to completion.

Respectfully submitted,



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